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10/511,505

10/14/2004

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EXAMINER

KILPATRICK, BRYAN T

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/511,505 | Applicant(s) WATLING ET AL. | |
| | Examiner BRYAN T. KILPATRICK | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,39 and 41-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The arguments/remarks filed on 29 June 2009 have been entered and fully considered.
2. No new amendments to the most recent set of instant claims have been made.
3. Claims 1-37 and 40 have been cancelled; and claims 38-39 and 41-61 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-39, 41-45, 47-49, and 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over W.O. 96/03768 (VESTAL et al.) as applied to claims 38-39, and further in view of U.S. Patent Application Publication 2004/0119010 (PERRYMAN et al.).

Instant claims 38 and 39 recite a method of quantifying a plurality of elements in a fluid sample adsorbed/absorbed onto or into an inert collection matrix comprised of exposing the sample to high energy radiation capable of ionization, measuring ionized elements in a portion of sample via mass spectrometry, exposing a matrix-matched Certified Reference Material (CRM) to high energy radiation for ionization of at least a portion of the CRM, and measuring and determining quantities of elements in an ionized sample via mass spectrometry. VESTAL et al. teaches, with respect to claim 1, an analysis - which includes detection, identification, and quantification - of any component that is present in a sample deposited on a support by way of ionization via high energy radiation in the form of laser pulses using mass spectrometry. VESTAL et al. teaches the use of an "appropriate matrix" that is dictated by the sample to be analyzed in the

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second paragraph of the Background of Invention section, page 1. VESTAL et al. teaches the use of internal standards, such as a CRM, in paragraph 3 of page 10.

Even though VESTAL et al. teaches the use of the appropriate matrix that is dictated by the sample, VESTAL et al. does not expressly state the absorbing/adsorbing of a sample onto or into a solid matrix. PERRYMAN et al. teaches the use of solid organic acids as matrix materials in paragraph [0057], and a crystallization method that produces analyte molecules in the matrix crystals in paragraphs [0123]-[0124]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the solid matrix materials of PERRYMAN et al. with the analysis method of VESTAL et al. since the method of combining an analyte or sample with a solid matrix is well-known in the art, paragraphs [0123] and [0126] of PERRYMAN et al.

Instant claim 41 recites the CRM is selected from the group consisting of SARM 1, 3, and 46; and SY-2. The examiner takes the position that a standard or CRM is a sample with a known outcome and is still a sample that can be considered to be a part of the plurality of samples to be analyzed by the system claim by VESTAL et al.; in addition, VESTAL et al. also teaches the use of internal standards in paragraph 3 of page 10.

Instant claim 42 recites a method wherein an inert collection matrix is part of a sample collection device comprising the matrix capable of absorbing and adsorbing a fluid sample, and a solid support wherein the matrix is affixed to an area of the support. These requirements are met by the method recited in claim 61 of VESTAL et al.

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Instant claim 43 recites that a collection matrix is selected from the group consisting of aragonite, aluminium hydroxide, titania, glucose, Starch "A", Starch "B", glucodin, cellulose powder/granules, fibrous cellulose, hydroxy butyl methyl cellulose, vegetable flour or mixtures thereof. Instant claim 44 recites the vegetable flour of instant claim 43 is selected from a group consisting of rice, maize, wheat, soy, rye, corn flour, or mixtures thereof. Instant claim 45 recites the collection matrix is fibrous cellulose. VESTAL et al. teaches on page 1, lines 20–23 in the Background of the Invention section the use of the “appropriate matrix” for analysis that does not limit the matrix to a particular type, but makes it dependent on the sample being analyzed.

Instant claims 47 and 48 recite the use of pre-calibrated analytes as internal standard. VESTAL et al. also teaches the use of internal standards in paragraph 3 of page 10.

Instant claim 49 recites the solid support has a bar-code with sample information. VESTAL et al. discloses this in line 25 of page 10.

Instant claim 52 recites the fluid sample is selected from body fluids, oils, and water. Instant claim 53 recites body fluid is selected from blood, urine, or sweat. VESTAL et al. discloses a claimed invention that analyzes liquid solution samples in page 1, paragraph 3; VESTAL et al. is not limited to any specific type of liquid solution sample. VESTAL et al. does not explicitly disclose that the samples are body fluids, oils, or water. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed invention of VESTAL et al. to analyze body

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fluids, oils, and water. The motivation would have been for conducting biological studies such as the Human Genome Project as discussed on pages 3-4.

Instant claims 54 and 55 recite sizes for samples to be less than about 100 microliters. VESTAL et al. discloses in line 19 of page 7 the use of a few microliters of sample solution that is dictated by the plate used. In addition, line 20 of page 8 discloses the use of 100 nanoliters of sample solution with 1024 sample spot plates as an example. Examiner takes the position that this limitation is dependent of the plate used for analysis.

Instant claim 56 recites the high energy radiation is UV laser radiation. Claim 1 of VESTAL et al. recites the use of a laser source for ionization. The examiner takes the position that the laser source is not just limited to UV radiation, but to any type of energy radiation.

Instant claim 57 recites laser radiation is a component of a mass spectrometer. The Abstract and claim 1 of VESTAL et al. disclose the use of laser source in a mass spectrometer.

Instant claim 58 recites the mass spectrometer is either a quadrupole or time-of-flight. VESTAL et al. explicitly discloses this in lines 18-20 of page 1.

Instant claim 59 recites the fluid sample is exposed to radiation for a period of from about 10 seconds to about 120 seconds. VESTAL et al. discloses on page 1, paragraph 3 that loading and analyzing a sample can take approximately five minutes. In addition, VESTAL et al. discloses that samples on a plate receive laser pulses as a

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function of the laser beam striking a particular sample in paragraph 4 of page 16, which further suggest the pulse time is sample dependent.

Instant claim 60 recites the elements to be detected and/or quantified are selected from dietary trace elements, toxic elements and markers of pollution or wear and tear. VESTAL et al. discloses on page 3, paragraph 1 that the samples analyzed by the claimed invention can vary and are dependent on the needs of the scientist or person operating the instrument.

Instant claim 61 recites the use of wells or indentations for fluid samples. VESTAL et al. explicitly discloses this in line 11 of page 7.

Claims 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over W.O. 96/03768 (VESTAL et al.) as applied to claims 38-39 above, and in view of “Structure of a Matrix Based on Polysaccharide Derivatives for the Immobilization of Biologically Active Substances” by BURKHANOVA et al.

Instant claim 46 recites the fibrous cellulose matrix is modified by oxidation and/or acid hydrolysis. VESTAL et al. teaches on page 1, lines 20–23 in the Background of the Invention section the use of the “appropriate matrix” for analysis that does not limit the matrix to a particular type, but makes it dependent on the sample being analyzed.

VESTAL et al. does not disclose the modification of the matrix. However, BURKHANOVA et al. discloses on page 488 “we took microcrystalline cellulose (MCC),

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obtained by acid hydrolysis from cotton cellulose, and U-type amylase” which meets the present limitations for the fibrous cellulose matrix of instant claim 46. It is the Examiner’s position the microcrystalline cellulose taught by BURKHANOVA et al. is in a different physical form than the claimed fibrous cellulose, but is chemically the same absent any evidence to the contrary. Furthermore, BURKHANOVA et al. discloses, “Chemical modification of the selected material was performed by specific oxidation with periodic acid and its salts.” It would have been obvious to one of ordinary skill in the art to use the matrix modification taught by BURKHANOVA et al. to modify the matrix of VESTAL et al. because of the ease of tailoring the cellulose to specific samples in enzymatic analyses, as disclosed on page 491, 5th paragraph of BURKHANOVA et al.

Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over W.O. 96/03768 (VESTAL et al.) as applied to claims 38-39 above, and in further view of U.S. Patent 5,777,324 (HILLENKAMP).

Instant claim 50 recites a sample collection device having a cover for a matrix. VESTAL et al. discloses the use of a sample support for receiving a sample on its surface in pages 7-9 in the section “Sample Receiving Surface.”

VESTAL et al. does not disclose that the plate is multilayered. However, HILLENKAMP discloses the use of a porous or fibrous cover for a matrix in lines 48-64 of column 8 and in Figures 9A-9B. It would have been obvious to one of ordinary skill in the art to use the cover of HILLENKAMP to modify the sample support of VESTAL et al.

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for the purpose of improved sample containment as explicitly stated in line 50 of column 8.

Instant claim 51 recites the sample collection device has multilayers where the collection matrix layer is sandwiched between two supporting layers with one having an opening exposing the matrix. This limitation is disclosed in lines 48-64 of column 8 and in Figures 9A-9B of HILLENKAMP.

Response to Arguments

Applicant's arguments/remarks filed 29 June 2009 have been fully considered but they are not persuasive.

In regards to p. 7-9 of Applicant's arguments/remarks concerning instant claims 38-39, 41-45, 47-49, and 52-61; Applicant states in p. 7, paragraph 2 that VESTAL et al. does not disclose mixing a sample with matrix and/or using a solid inert collection matrix. Then, in p. 7, paragraph 3, Applicant states that VESTAL et al. mentions sample preparation using a matrix; however, the matrix is a solution.

As previously stated above, the second paragraph of the Background of Invention section on page 1 of VESTAL et al. teaches the use of an "appropriate matrix" that is dictated by the sample to be analyzed. Then, Examiner introduces PERRYMAN et al. to show the use of solid organic acids as matrix materials in paragraph [0057], and techniques of employing solid matrix materials in paragraphs [0123]-[0126]. In light of

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the broadest interpretation of the instant claims (since the instant claims do not limit how a sample is adsorbed/absorbed into or onto a matrix), PERRYMAN et al. does disclose adsorbing/absorbing a sample onto or into a matrix in the form of the dried analyte-doped matrix crystal disclosed in paragraph [0123] of PERRYMAN et al.

Applicant states on p. 9, paragraph 2 that there is no motivation in either VESTAL et al. or PERRYMAN et al. to modify methods therein. The Examiner disagrees with this statement. As previously cited, the second paragraph of the Background of Invention section, page 1 of VESTAL et al. teaches the use of an “appropriate matrix” that is dictated by the sample to be analyzed, and PERRYMAN et al. discloses the use of solid organic acids as matrix materials in paragraph [0057]. As previously stated, PERRYMAN et al. discloses adsorbing/absorbing a sample onto or into a matrix in the form of the analyte-doped matrix crystal disclosed in paragraph [0123], and further states that the dried-droplet method is the oldest and preferred sample preparation method in the field of MALDI in paragraph [0126]. In light of these previously disclosed statements, Examiner maintains that it would have been obvious to combine VESTAL et al. and PERRYMAN et al.

In regards to p. 9-10 of Applicant’s arguments/remarks concerning instant claim 46, Applicant states that the combination of VESTAL et al. and BURKHANOVA et al. does not disclose the limitations of instant claim 46.

As previously stated above, VESTAL et al. teaches (on page 1, lines 20–23 in the Background of the Invention section) the use of the “appropriate matrix” for analysis,

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which does not limit the matrix to a particular type, but makes it dependent on the sample being analyzed. BURKHANOVA et al. discloses on page 488 “we took microcrystalline cellulose (MCC), obtained by acid hydrolysis from cotton cellulose, and U-type amylase” which meets the present limitations for the fibrous cellulose matrix of instant claim 46. It is the Examiner’s position the microcrystalline cellulose taught by BURKHANOVA et al. is in a different physical form than the claimed fibrous cellulose, but is chemically the same absent any evidence to the contrary. Furthermore, BURKHANOVA et al. discloses, “Chemical modification of the selected material was performed by specific oxidation with periodic acid and its salts.” Examiner maintains that it would have been obvious to one of ordinary skill in the art to use the matrix modification taught by BURKHANOVA et al. to modify the matrix of VESTAL et al. because of the ease of tailoring the cellulose to specific samples in enzymatic analyses, as disclosed on page 491, 5th paragraph of BURKHANOVA et al.

In regards to p. 10-11 of Applicant’s arguments/remarks concerning instant claims 50-51, Applicant states that the combination and/or singular use of VESTAL et al. or HILLENKAMP does not teach the limitations of instant claims 50-51. VESTAL et al. teaches on page 1, lines 20–23 in the Background of the Invention section the use of the “appropriate matrix” for analysis using a mass spectrometer (inside a vacuum system) that does not limit the matrix to a particular type, but makes it dependent on the sample being analyzed. As previously discussed, PERRYMAN et al. discloses adsorbing/absorbing a sample onto or into a matrix in the form of the analyte-doped

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matrix crystal disclosed in paragraph [0123], and further states that the dried-droplet method is the oldest and preferred sample preparation method in the field of MALDI in paragraph [0126]. VESTAL et al. discloses the combination of the matrix and analyte in a vacuum system - vacuum systems are well known in the field of MALDI as a drying source for improving the dried-droplet method (see paragraphs [0142]-[0143] of PERRYMAN et al. for an example). In light of the broadest interpretation of the instant claims (since the instant claims do not limit how a sample is adsorbed/absorbed into or onto a matrix) and VESTAL et al. employing a vacuum system, the combination of VESTAL et al. and HILLENKAMP discloses adsorbing/absorbing a sample onto or into a matrix. Furthermore, as previously stated, it would have been obvious to one of ordinary skill in the art to use the cover of HILLENKAMP to modify the sample support of VESTAL et al. with the motivation being to improve sample containment as explicitly stated in line 50 of column 8 of HILLENKAMP.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797

/B. T. K./
Examiner, Art Unit 1797